



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/519,959 03/07/00 CARRASCO

N 96700/488

HM12/0119

EXAMINER

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90 Park Avenue
New York NY 10016

RAWLINGS, S

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

01/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/519,959

Applicant(s)

CARRASCO ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Restriction Election facsimile sheet*.

DETAILED ACTION

1. Claims 1-28 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions

Elections/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-6, drawn to a method of diagnosis wherein the expression of mgNIS is detected using an agent that is reactive with mgNIS, classified in class 424, subclass 9.2 and class 435, subclass 7.23.

Group II. Claims 1 and 7-9, drawn to a method of diagnosis wherein the expression of mgNIS is detected using a nucleic acid probe, classified in class 435, subclass 6.

- Group III. Claims 1 and 10-11, drawn to a method of diagnosis wherein the expression of mgNIS is detected using a detectable agent that is selectively taken up by mgNIS, classified in class 424, subclass 1.37.
- Group IV. Claims 12-13, drawn to a method of treatment wherein a diagnosis is first rendered by detecting the expression of mgNIS, classified in class 424, subclass 9.1.
- Group V. Claims 12-15, drawn to a method of treatment wherein a diagnosis is first rendered by detecting the expression of mgNIS and wherein the method of treatment is radiotherapy comprising administering radioiodide, classified in class 424, subclass 1.37.
- Group VI. Claims 12 and 16-17, drawn to a method of treatment wherein a diagnosis is first rendered by detecting the expression of mgNIS and wherein the method of treatment comprises administering an anti-cancer agent that is reactive with mgNIS, classified in class 424, subclass 181.1.
- Group VII. Claims 18-23, drawn to a method of assessing the efficacy of therapy comprising detecting the expression of mgNIS using an immunoassay, classified in class 424, subclass 9.2 and class 424, subclass 9.2.
- Group VIII. Claims 18 and 24-26, drawn to a method of assessing the efficacy of therapy comprising detecting the expression of mgNIS using a nucleic acid probe, classified in class 435, subclass 6.

Group IX. Claims 18 and 27-28, drawn to a method of assessing the efficacy of therapy comprising detecting the expression of mgNIS using a detectable agent that is selectively taken up by mgNIS, classified in class 424, subclass 1.37.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Groups III and IX are further subject to an election of a single disclosed species.

Claims 11 and 28 are generic to a plurality of disclosed patentably distinct species comprising (a) radioiodide and (b) ^{99m}Tc -pertechnetate. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

7. Group IV is further subject to an election of a single disclosed species.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising (a) surgery, (b) radiotherapy, (c) hormone therapy, (d) chemotherapy, and (e) any one combination of the foregoing species of treatment. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. If Applicant elects species (e), Applicant is required to identify and elect a specific combination of treatments to be examined.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37

C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Art Unit 1642

slr

January 16, 2001



ANTHONY G. CAPUTO
SUPERVISORY PATENT EXAMINER
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